



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY-DOCKET NO.	CONFIRMATION NO.
10/823,456	04/12/2004	Patrice Nazzaro	760-182	4710
23869	7590	01/10/2008		
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/823,456

Applicant(s)

NAZZARO, PATRICE

Examiner

Brian E. Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57, 59-64 and 79-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57, 59-64 and 79-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,6,7,10-21,24-29,31,32,35,36,38-41,44-46,79,80,82,83,85,89,91 are rejected under 35 U.S.C. 102(b) as being anticipated by Liebig et al. (4517687). Fig. 1 shows a vascular graft material formed of a double velour (col. 3, line 22) weave having a plurality of warp yarns **14** and a plurality of fill yarns **13**. Fig. 3 shows a radially crimped graft with first and second same diameter sections having third greater diameter bulbous sections positioned between throughout its length and a second end with two lumens. The Examiner interprets the "generally spherical" bulbous sections to have a greater number of warp yarns because its diameter is greater than the non-bulbous sections, thus having more yarns required to form a bulbous section. Liebig discloses the woven material is a polyester, col. 2, lines 13-18. Liebig also discloses the warp and fill yarns can be double ply and 40 denier, col. 3, lines 59,60. Liebig additionally discloses (col. 2, lines 18-21) that different yarn materials can be used, which would result in portions with different deniers and types. Regarding claims 82, 85, 91, the Examiner interprets the bulbous sections to vary the warp yarns in its section with the greatest amount required at the largest diameter section and less yarns at the narrow points.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 4,5,22,23,33,34,42,43,47-56,59-64,86,88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebig et al. '687 in view of Nunez et al. (5800514). Liebig et al. is explained supra. However, Liebig et al. fail to disclose the dimensions or diameters of the graft. Nunez et al. teach (Fig. 3) a woven vascular graft having a larger diameter section and a smaller diameter section with the smaller diameter being about 10mm and the larger diameter being 2mm greater than the smaller, col. 7, lines 60-66. It would have been obvious to one of ordinary skill in the art to use the dimensions or diameters of a graft for the sections as taught by Nunez et al. with the graft of Liebig et al. such that it could result in a more closely matching contour to the vessel in which it is placed.

Regarding claims 22,23,42,43,49,50 Liebig does disclose the number of warp yarns is greater than the fill yarns, col. 2, lines 38-40. However, Liebig et al. fail to disclose the first end of the bulbous portion includes an increase of at least three more warp yarns than fill yarns and the second end decreases by three warp yarns to every two fill yarns. Nunez et al. teach that seamless grafts are formed with an equal number of warp yarns increasing at one end to the other end decreasing, col. 9, lines 12-18. Nunez also teaches there are at least three warp yarns per two fill yarns, col. 10, lines 35-37,53-56,63-65. It would have been obvious to one of ordinary skill in the art to use the teaching of keeping equivalent warp yarns increased at one end of a section such

Art Unit: 3738

as the larger diameter portion as the number of warp yarns at the second end of the section as taught by Nunez et al. in the graft of Liebig et al. so that the wall is made contiguous. It would have been an obvious to one of ordinary skill in the art to use three warp yarns to two fill yarns as taught by Nunez with the graft of Liebig for providing a seamless structure.

Claims 8,9,30,37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebig et al. '687 in view of De Paulis (6352554). Liebig et al. is explained supra. However, Liebig et al. fail to disclose the portion of the graft being bulbous has a different pattern or includes a valve. De Paulis teaches (Fig. 5) a vascular graft having a valve in a bulbous, different pattern section of a graft. De Paulis also teaches that the different pattern (col. 5, lines 28-30) enables the graft to enable pressure to be reduced at the coronary ostia, col. 6, lines 42-45. It would have been obvious to one of ordinary skill in the art to use a different pattern and valve as taught by De Paulis in the graft of Liebig et al. such that it can be used in the coronary ostia when repairing an aorta.

Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liebig et al. '687 in view of Nunez et al. '514 as applied to claim 55 above, and further in view of De Paulis '554. Liebig et al. in view of Nunez et al. is explained as before. DePaulis is explained above. However, Liebig as modified by Nunez et al. fail to disclose the sections of the graft having different patterns. It would have been obvious to one of ordinary skill in the art to use a different pattern and valve as taught by De Paulis in the graft of Liebig et al. as modified by Nunez et al. such that it can be used in the coronary ostia when repairing an aorta.

Claims 81,84,90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liebig et al. '687 in view of Yachia et al. (2004/93065). Liebig et al. is explained supra. However, Liebig et al. fail to disclose the portion of the graft being bulbous has an oblong shape. Yachia et al. teach (Fig. 6) a graft liner that has an oblong bulbous middle section between two tubular ends. Yachia also teaches that the bulbous oblong section is designed to accommodate the peristaltic waves in organs without impeding their function, Paragraph 18. It would have been obvious to one of ordinary skill in the art to utilize the structure of a bulbous oblong central section as taught by Yachia et al. with the graft of Liebig et al. such that it is designed to accommodate the vessel functions the graft is implanted therein.

Claim 87 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liebig et al. '687 in view of Nunez et al. '514 as applied to claim 49 above, and further in view of Yachia et al. (2004/93065). Liebig et al. in view of Nunez et al. is explained supra. However, Liebig as modified by Nunez fail to disclose an oblong central section between two tubular portions. Yachia et al. is explained as above. It would have been obvious to one of ordinary skill in the art to utilize graft structure to match the vessel dimensions and anatomical shape to be oblong in the central region as taught by Yachia et al. with the graft of Liebig et al. as modified by Nunez et al. such that it enables proper function in the repair site.

Response to Arguments

Applicant's arguments filed 9/17/07 have been fully considered but they are not persuasive. Applicant argues that Liebig fails to disclose a greater number of warp yarns are used for the bulbous portion than the tubular portions. However, the Examiner interprets the larger bulbous portions require more yarns since they have a greater diameter, thus, there is a greater number of warp yarns at the bulbous portion.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Thus, the use of Nunez teachings can be combined with Liebig such that it provides a stable construction that will not become unwoven within the patient under anatomical stresses and allows for changes in dimensions of the graft diameter without compromising its structure.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). So first it should be mentioned the DePaulis reference was used for its teaching

Art Unit: 3738

that the pattern must be changed when accommodating the graft with a valve. Thus, Liebig's device was not modified with DePaulis design as alleged by the arguments, but could be said to use the teaching to have structural stability established in a bulbous region where a valve is placed. So in other words more yarns would be placed in the bulbous region to accommodate the valve integrated therein, but not use separate sections as Applicant alleged.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3738

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boyce (WO 97/40755) teaches a graft with elongate sections having a bulbous middle section. Yachia (5246495) teaches a stent with spherical bulbous central sections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (8:30am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

